IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

IN RE: DIET DRUGS (PHENTERMINE/ FENFLURAMINE/DEXFENFLURAMINE) PRODUCTS LIABILITY LITIGATION	)	MDL NO. 1203
THIS DOCUMENT RELATES TO:	)	
SHEILA BROWN, et al.	)	
v.	)	CIVIL ACTION NO. 99-20593
AMERICAN HOME PRODUCTS CORPORATION	)	2:16 MD 1203

MEMORANDUM IN SUPPORT OF SEPARATE PRETRIAL ORDER NO. 9155

Bartle, J. October 9, 2013

Kenneth Harley ("Mr. Harley" or "claimant"), a class member under the Diet Drug Nationwide Class Action Settlement Agreement ("Settlement Agreement") with Wyeth,[1] seeks benefits from the AHP Settlement Trust ("Trust"). Based on the record developed in the show cause process, we must determine whether claimant has demonstrated a reasonable medical basis to support his claim for Matrix Compensation Benefits ("Matrix Benefits").[2]

---

1. Prior to March 11, 2002, Wyeth was known as American Home Products Corporation. In 2009, Pfizer, Inc. acquired Wyeth.

2. Matrix Benefits are paid according to two benefit matrices (Matrix "A" and Matrix "B"), which generally classify claimants for compensation purposes based upon the severity of their medical conditions, their ages when they are diagnosed, and the presence of other medical conditions that also may have caused or contributed to a claimant's valvular heart disease ("VHD"). See Settlement Agreement §§ IV.B.2.b. & IV.B.2.d.(1)-(2). Matrix A-1 describes the compensation available to Diet Drug Recipients with

(continued...)

To seek Matrix Benefits, a claimant must first submit a completed Green Form to the Trust. The Green Form consists of three parts. The claimant or the claimant's representative completes Part I of the Green Form. Part II is completed by the claimant's attesting physician, who must answer a series of questions concerning the claimant's medical condition that correlate to the Matrix criteria set forth in the Settlement Agreement. Finally, claimant's attorney must complete Part III if claimant is represented.

In May, 2002, claimant submitted a completed Green Form to the Trust signed by his attesting physician, Mitchell Greenspan, M.D. Based on echocardiograms dated April 1, 1999 and May 25, 1999, Dr. Greenspan attested in Part II of Mr. Harley's Green Form that he suffered from moderate mitral regurgitation, an abnormal left atrial dimension, and a reduced ejection fraction in the range of 50% to 60%.[3] Based on such findings,

---

2. (...continued)
serious VHD who took the drugs for 61 days or longer and who did not have any of the alternative causes of VHD that made the B matrices applicable. In contrast, Matrix B-1 outlines the compensation available to Diet Drug Recipients with serious VHD who were registered as having only mild mitral regurgitation by the close of the Screening Period or who took the drugs for 60 days or less or who had factors that would make it difficult for them to prove that their VHD was caused solely by the use of these Diet Drugs.

3. Dr. Greenspan also attested that claimant suffered from moderate aortic regurgitation and New York Heart Association Functional Class II symptoms. These conditions are not at issue in this claim.

claimant would be entitled to Matrix A-1, Level II benefits in the amount of $518,044.[4]

In the report of claimant's April 1, 1999 echocardiogram, the reviewing cardiologist, J. Phillip Moyer, M.D., F.A.C.C., concluded that "Doppler analysis also demonstrates moderate [mitral regurgitation]." In the report of claimant's May 25, 1999 echocardiogram, Dr. Moyer stated, "Doppler analysis demonstrates moderate [mitral regurgitation]." Dr. Moyer, however, did not specify a percentage as to claimant's level of mitral regurgitation in either the April 1, 1999 echocardiogram or the May 25, 1999 echocardiogram. Under the definition set forth in the Settlement Agreement, moderate or greater mitral regurgitation is present where the Regurgitant Jet Area ("RJA") in any apical view is equal to or greater than 20% of the Left Atrial Area ("LAA"). See Settlement Agreement § I.22.

In April, 2003, the Trust forwarded the claim for review by Waleed N. Irani, M.D., one of its auditing cardiologists. In audit, Dr. Irani concluded that there was no reasonable medical basis for the attesting physician's finding

---

4. Under the Settlement Agreement, a claimant is entitled to Level II benefits for damage to the mitral valve if he or she is diagnosed with moderate or severe mitral regurgitation and one of five complicating factors delineated in the Settlement Agreement. See Settlement Agreement § IV.B.2.c.(2)(b). Although the Trust disputes that claimant had an abnormal left atrial dimension or a reduced ejection fraction, each of which is one of the complicating factors needed for a Level II claim, we need not resolve these issues given our determination with respect to claimant's level of mitral regurgitation.

that claimant had moderate mitral regurgitation because his May 25, 1999 echocardiogram demonstrated only mild mitral regurgitation.[5] In support of this conclusion, Dr. Irani stated that claimant had "[m]ild [mitral regurgitation] at worst."

Based on the auditing cardiologist's finding that claimant did not have moderate mitral regurgitation, the Trust issued a post-audit determination denying Mr. Harley's claim. Pursuant to the Rules for the Audit of Matrix Compensation Claims ("Audit Rules"), claimant contested this adverse determination.[6] In contest, claimant submitted reports prepared by Dr. Nicholas L. DePace, M.D., F.A.C.C. for echocardiograms dated May 25, 1999,[7] January 28, 2000, and February 14, 2003.[8] Claimant stated that Dr. DePace "concluded that Mr. Harley has Fen-Phen induced

---

5. Dr. Irani apparently did not review claimant's April 1, 1999 echocardiogram.

6. Claims placed into audit on or before December 1, 2002 are governed by the Policies and Procedures for Audit and Disposition of Matrix Compensation Claims in Audit, as approved in Pretrial Order ("PTO") No. 2457 (May 31, 2002). Claims placed into audit after December 1, 2002 are governed by the Audit Rules, as approved in PTO No. 2807 (Mar. 26, 2003). There is no dispute that the Audit Rules contained in PTO No. 2807 apply to Mr. Harley's claim.

7. Dr. DePace noted that claimant had "[m]oderate mitral insufficiency" with an RJA/LAA ratio of 23%.

8. The reports of claimant's January 28, 2000 and February 14, 2003 echocardiograms do not assist claimant in meeting his burden of proving that there is a reasonable medical basis for Dr. Greenspan's finding of moderate mitral regurgitation based on Mr. Harley's April 1, 1999 and May 25, 1999 echocardiograms. In any event, it does not appear that claimant provided copies of the tapes of these echocardiograms for review by the Trust.

valvulopathy, and he has moderate mitral valve regurgitation ...."

Although not required to do so, the Trust forwarded the claim to the auditing cardiologist for a second review. Dr. Irani submitted a declaration in which he affirmed his previous conclusion that there was no reasonable medical basis for Dr. Greenspan's finding that Mr. Harley had moderate mitral regurgitation because claimant only had mild mitral regurgitation. Specifically, Dr. Irani stated, in pertinent part, that:

> In accordance with the Trust's request, I reviewed Claimant's claim file and echocardiogram tape for a second time. In connection with my review, I determined that Claimant's mitral regurgitation is clearly mild. I digitized the echocardiogram tape, and accurately measured the mitral regurgitant jet area in the only frame with a representative jet and concluded that the regurgitant jet area measures 3.68 cm^2. I accurately measured the left atrial area in the only apical four-chamber view shown on the tape and determined that the left atrial area measures 25.43 cm^2. Accordingly, the regurgitant jet area/left atrial area ratio based on these measurements is 14.5%.

(Internal citations omitted.)

The Trust then issued a final post-audit determination, again denying Mr. Harley's claim. Claimant disputed this final determination and requested that the claim proceed to the show cause process established in the Settlement Agreement. See Settlement Agreement § VI.E.7.; PTO No. 2807, Audit Rule 18(c). The Trust then applied to the court for issuance of an Order to

show cause why Mr. Harley's claim should be paid. On January 26, 2004, we issued an Order to show cause and referred the matter to the Special Master for further proceedings. See PTO No. 3226 (Jan. 26, 2004).

Once the matter was referred to the Special Master, the Trust submitted its statement of the case and supporting documentation. Claimant then served a response upon the Special Master. The Trust submitted a reply on March 22, 2004. Under the Audit Rules, it is within the Special Master's discretion to appoint a Technical Advisor[9] to review claims after the Trust and claimant have had the opportunity to develop the Show Cause Record. See Audit Rule 30. The Special Master assigned a Technical Advisor, Gary J. Vigilante, M.D., F.A.C.C., to review the documents submitted by the Trust and claimant and to prepare a report for the court. The Show Cause Record and Technical Advisor Report are now before the court for final determination. See id. Rule 35.

The issue presented for resolution of this claim is whether claimant has met his burden of proving that there is a reasonable medical basis for the attesting physician's finding that he had moderate mitral regurgitation. See id. Rule 24.

---

9. A "[Technical] [A]dvisor's role is to act as a sounding board for the judge--helping the jurist to educate himself in the jargon and theory disclosed by the testimony and to think through the critical technical problems." Reilly v. United States, 863 F.2d 149, 158 (1st Cir. 1988). In a case such as this, where conflicting expert opinions exist, it is within the discretion of the court to appoint a Technical Advisor to aid it in resolving technical issues. Id.

Ultimately, if we determine that there is no reasonable medical basis for the answer in claimant's Green Form that is at issue, we must affirm the Trust's final determination and may grant such other relief as deemed appropriate. See id. Rule 38(a). If, on the other hand, we determine that there is a reasonable medical basis for the answer, we must enter an Order directing the Trust to pay the claim in accordance with the Settlement Agreement. See id. Rule 38(b).

In connection with his request that this claim proceed to show cause, Mr. Harley submitted a September 8, 2003 letter from Dr. DePace, wherein he stated, in pertinent part, that:

> As can be seen this patient had three echocardiograms. The third [echocardiogram] was technically excellent. The other two were somewhat suboptimal, especially the second. In the second [echocardiogram] we could not discern the mitral regurgitation jet fully because it was technically poor in quality. That is not to say that the mitral regurgitation decreased even though it calculated at only 11%. It was just not well seen. That last [echocardiogram] which showed the mitral regurgitation jet clearly was at least 30% of the left atrial area. We also noted that there is a bicuspid aortic valve. The aortic gradients have been going up progressively from 4 to 16 to 25 mmHg.
>
> This patient absolutely has a Phen-Fen valvulopathy. The mitral valve shows moderate mitral regurgitation within a large atrium and he would make the grid on that basis.... [T]he strength of the case obviously is in the mitral regurgitation with a large left atrium which makes the grid and definitely shows end organ damage from this Phen-Fen valvulopathy.

In further support of his claim, Mr. Harley argues that he has established a reasonable medical basis for his claim because four board-certified cardiologists have concluded that he has moderate mitral regurgitation. In response, the Trust argues that, based on the findings of the auditing cardiologist, claimant did not establish a reasonable medical basis for his claim.[10]

The Technical Advisor, Dr. Vigilante, reviewed claimant's May 25, 1999 echocardiogram and concluded that there was no reasonable medical basis for the attesting physician's finding that claimant had moderate mitral regurgitation. Specifically, Dr. Vigilante stated, in pertinent part, that:

> I reviewed the Claimant's echocardiogram of May 25, 1999 in detail. This was a below average study.... This was a tape of several loops. There were very limited views of mitral regurgitation.... Mild centrally located mitral regurgitation was noted in the parasternal long-axis view, apical four chamber view, and apical two chamber view. The Doppler evaluation of the mitral regurgitation jet in the apical four chamber view was of poor quality and was noted to be in only one cardiac cycle. This was an off axis view. The RJA/LAA ratio was less than 16% even after the images were digitized. The RJA/LAA ratio never approached 20% in this study.... I am unable to determine how

---

10. The Trust also argues that the Court should not consider Dr. DePace's letter in resolving the present claim because it was not verified and, under Rule 26(a)(2) of the Federal Rules of Civil Procedure, Dr. DePace was required to disclose his qualifications, compensation and a list of cases in which he has served as an expert. We previously have rejected these arguments. See, e.g., Mem. in Supp. of PTO No. 8956, at 8 n.9 (Nov. 6, 2012); Mem. in Supp. of PTO No. 8480, at 7 n.10 (Jun. 4, 2010).

> Dr. DePace calculated a RJA/LAA ratio of 23%....
>
> ... [T]here is no reasonable medical basis for the Attesting Physician's answer to Green Form Question C.3.a. That is, the echocardiogram of May 25, 1999 demonstrated mild mitral regurgitation with comments as above. The RJA/LAA never approached 20% in this study. An echocardiographer could not reasonably conclude that moderate mitral regurgitation was present on this study even taking into account inter-reader variability.

The Technical Advisor, Dr. Vigilante, subsequently reviewed claimant's April 1, 1999 echocardiogram and issued an addendum to the Technical Advisor Report wherein he concluded that there was no reasonable medical basis for the attesting physician's finding that claimant had moderate mitral regurgitation. Dr. Vigilante stated, in pertinent part, that:

> I reviewed the tape of the Claimant's echocardiogram of April 1, 1999.... This was an adequate quality study and improved compared to the previously analyzed echocardiogram of May 25, 1999. The study of April 1, 1999 demonstrated the usual echocardiographic views. There was reasonable demonstration of the mitral regurgitant jet in the apical four chamber view although there were only a couple of cardiac cycles in the apical two chamber view that demonstrated the [mitral regurgitant] jet. The Nyquist limit was appropriately set at 60 cm per second at a depth of 24 cm in the apical four chamber view.
>
> Visually, the mitral valve appeared mildly thickened. The leaflets opened and closed adequately. There was no evidence of mitral valve prolapse or mitral annular calcification. I digitized the cardiac cycles in the apical four and two chamber views in which the mitral regurgitant jet appeared the most significant. I planimetered several representative RJAs and

> the representative LAA. Visually, there appeared to be mild mitral regurgitation. The largest representative RJA in the apical four chamber view was 2.1 cm2. This was a thin jet that traveled laterally into the left atrium. The RJA was even less in the apical two chamber view. The largest representative LAA in the apical four chamber view was 23.8 cm2. Therefore, the largest representative RJA/LAA ratio was 9%, diagnostic of mild mitral regurgitation. There were no sonographer-determined RJAs on this study.
>
> ....
>
> ... [T]here is no reasonable medical basis for the Attesting Physician's answer to Green Form Question C.3.a., based on the Claimant's April 1, 1999 echocardiogram. That is, this echocardiographic study demonstrated mild mitral regurgitation with comments as above. The RJA/LAA ratio never approached 20% on this study. An echocardiographer could not reasonably conclude that moderate mitral regurgitation was present on this study even taking into account inter-reader variability.

In response to the addendum to the Technical Advisor Report, claimant argues that we should accept the finding of the attesting physician because Dr. Greenspan was claimant's treating physician and, as such, he was in the "better position" to review claimant's echocardiograms.[11] Claimant also argues that he should prevail because it is undisputed that there is inter-reader variability when reviewing echocardiograms.

---

11. In his response to the initial Technical Advisor Report, claimant requested leave to conduct discovery of the Technical Advisor. Discovery, however, is precluded by the Audit Rules. See Audit Rule 41.

Finally, claimant argues that the Technical Advisor's conclusions do not aid the Court.[12]

After reviewing the entire Show Cause Record, we find claimant's arguments are without merit. First, claimant does not adequately refute the specific conclusions of the auditing cardiologist or the Technical Advisor as to his level of mitral regurgitation. Claimant does not rebut the auditing cardiologist's determination that the only representative jet on Mr. Harley's May 25, 1999 echocardiogram revealed only mild mitral regurgitation. Nor does he adequately challenge the Technical Advisor's conclusions that claimant's RJA/LAA ratio "never approached 20%" on claimant's May 25, 1999 echocardiogram, the measurement of claimant's mitral regurgitation in one view was done in "an off axis view," and claimant's April 1, 1999 echocardiogram revealed only mild mitral regurgitation.[13] Further, neither claimant nor his attesting physician identified any particular error with the findings of the auditing cardiologist and the Technical Advisor. Mere disagreement with the auditing cardiologist or the Technical Advisor without identifying any specific errors by them is insufficient to meet a

---

12. Claimant also argues that he should have been permitted to submit a report from the attesting physician with his response to the addendum to the Technical Advisor Report. We previously have explained that such reports are not permitted by Audit Rule 34. See, e.g., Mem. in Supp. of PTO No. 9041, at 9-10 n.11 (Apr. 5, 2013).

13. For this reason as well, we reject claimant's argument that the attesting physician was in "the better position" to review claimant's echocardiograms.

claimant's burden of proof. Indeed, despite arguing that his April 1, 1999 echocardiogram was the echocardiogram that formed the basis of his Green Form, claimant never had his expert, Dr. DePace, review this echocardiogram.

Moreover, claimant's reliance on inter-reader variability to establish a reasonable medical basis for the attesting physician's representation that Mr. Harley had moderate mitral regurgitation is also misplaced. The concept of inter-reader variability is already encompassed in the reasonable medical basis standard applicable to claims under the Settlement Agreement. In this instance, the attesting physician's opinion cannot be medically reasonable where claimant did not adequately rebut the conclusions of the auditing cardiologist and the Technical Advisor that Mr. Harley's RJA/LAA ratios were all less than 20%. Adopting claimant's position regarding inter-reader variability would allow a claimant to recover Matrix Benefits when his or her level of mitral regurgitation is below the threshold established by the Settlement Agreement. This result would render meaningless this critical provision of the Settlement Agreement.[14]

Finally, we reject claimant's assertion that the Technical Advisor did not aid the court "and simply injects

---

14. Moreover, the Technical Advisor took into account the concept of inter-reader variability as reflected in his statements, with respect to each echocardiogram, that "[a]n echocardiographer could not reasonably conclude that moderate mitral regurgitation was present on this study even taking into account inter-reader variability."

another cardiologist's opinion in the mix." To the contrary, the Technical Advisor found, and claimant did not adequately dispute, that there was no reasonable medical basis for Dr. Greenspan's Green Form representation of moderate mitral regurgitation. Specifically, the Technical Advisor detailed the erroneous measurements in claimant's May 25, 1999 echocardiogram and determined that the largest representative jet on claimant's April 1, 1999 echocardiogram revealed only mild regurgitation of 9%.

For the foregoing reasons, we conclude that claimant has not met his burden of proving that there is a reasonable medical basis for finding that he had moderate mitral regurgitation. Therefore, we will affirm the Trust's denial of Mr. Harley's claim for Matrix Benefits.